

AD _____

GRANT NUMBER: DAMD17-94-J-4438

TITLE: Population-Based Mammography Registry

PRINCIPAL INVESTIGATOR: Bonnie C. Yankaskas, Ph.D.

CONTRACTING ORGANIZATION: University of North Carolina at Chapel
Hill
Chapel Hill, North Carolina 27599-4100

REPORT DATE: October 1995

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for public release;
distribution unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

19960123 104

DTIC QUALITY INSPECTED 1

REPORT DOCUMENTATION PAGE			Form Approved OMB No. 0704-0188	
Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302, and to the Office of Management and Budget, Paperwork Reduction Project (0704-0188), Washington, DC 20503.				
1. AGENCY USE ONLY (Leave blank)		2. REPORT DATE October 1995		3. REPORT TYPE AND DATES COVERED Annual 30 Sep - 29 Sep 95
4. TITLE AND SUBTITLE Population-Based Mammography Registry			5. FUNDING NUMBERS DAMD17-94-J-4438	
6. AUTHOR(S) Bonnie C. Yankaskas, Ph.D.				
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) University of North Carolina at Chapel Hill Chapel Hill, North Carolina 27599-4100			8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012			10. SPONSORING/MONITORING AGENCY REPORT NUMBER	
11. SUPPLEMENTARY NOTES				
12a. DISTRIBUTION / AVAILABILITY STATEMENT Approved for public release; distribution unlimited			12b. DISTRIBUTION CODE	
13. ABSTRACT (Maximum 200 words) <p>The main objective of this infrastructure project is to expand a population-based mammography registry to include every mammograms performed in a 24 county are of North Carolina, which has a large rural, and black population and link pathology data, mammography diagnostic data, outcome data and quality data to study the patterns or use of mammography, and the patterns of practice of mammography in this distinct geographic region.</p> <p>In the first year we have accomplished much. The application software has been improved with better documentation, reporting and query additions, and allowance for expansion. A module has been instituted that aids practices in meeing FDA/ MQSA guidelines. We have developed materials in support of the data system being used by our participating practices. An extensive quality control system is now in practice. We have instituted strict rules for guaranteeing confidentiality of all data and we are working with the state and the National Breast Cancer Surveillance Consortium to find the best approach to protect our contributing radiologists, and the patient information from disclosure. We have enrolled 29 practices in 15 counties and and contacted all facilities in the 24 counties. We have linked up with the North Carolina Breast Cancer Study, (Breast Cancer SPORE), and the NCCCR are receiving all fast reported breast cancers in the 24 counties and are working with the NC Association of Tumor Registrars to create a mechanism for receiving all benign pathology data. In addition to all this activity, the creation of this infrastructure enabled us to successfully compete for funding by the National Cancer Institute to become part of the National Breast Cancer Consortium. This moves the project from local stature to national stature.</p>				
14. SUBJECT TERMS Mammography, Population-Based Registry, Screening Breast Cancer			15. NUMBER OF PAGES 9	
			16. PRICE CODE	
17. SECURITY CLASSIFICATION OF REPORT Unclassified	18. SECURITY CLASSIFICATION OF THIS PAGE Unclassified	19. SECURITY CLASSIFICATION OF ABSTRACT Unclassified	20. LIMITATION OF ABSTRACT Unlimited	

GENERAL INSTRUCTIONS FOR COMPLETING SF 298

The Report Documentation Page (RDP) is used in announcing and cataloging reports. It is important that this information be consistent with the rest of the report, particularly the cover and title page. Instructions for filling in each block of the form follow. It is important to **stay within the lines** to meet **optical scanning requirements**.

Block 1. Agency Use Only (Leave blank).

Block 2. Report Date. Full publication date including day, month, and year, if available (e.g. 1 Jan 88). Must cite at least the year.

Block 3. Type of Report and Dates Covered. State whether report is interim, final, etc. If applicable, enter inclusive report dates (e.g. 10 Jun 87 - 30 Jun 88).

Block 4. Title and Subtitle. A title is taken from the part of the report that provides the most meaningful and complete information. When a report is prepared in more than one volume, repeat the primary title, add volume number, and include subtitle for the specific volume. On classified documents enter the title classification in parentheses.

Block 5. Funding Numbers. To include contract and grant numbers; may include program element number(s), project number(s), task number(s), and work unit number(s). Use the following labels:

C - Contract	PR - Project
G - Grant	TA - Task
PE - Program Element	WU - Work Unit Accession No.

Block 6. Author(s). Name(s) of person(s) responsible for writing the report, performing the research, or credited with the content of the report. If editor or compiler, this should follow the name(s).

Block 7. Performing Organization Name(s) and Address(es). Self-explanatory.

Block 8. Performing Organization Report Number. Enter the unique alphanumeric report number(s) assigned by the organization performing the report.

Block 9. Sponsoring/Monitoring Agency Name(s) and Address(es). Self-explanatory.

Block 10. Sponsoring/Monitoring Agency Report Number. (If known)

Block 11. Supplementary Notes. Enter information not included elsewhere such as: Prepared in cooperation with...; Trans. of...; To be published in.... When a report is revised, include a statement whether the new report supersedes or supplements the older report.

Block 12a. Distribution/Availability Statement. Denotes public availability or limitations. Cite any availability to the public. Enter additional limitations or special markings in all capitals (e.g. NOFORN, REL, ITAR).

DOD - See DoDD 5230.24, "Distribution Statements on Technical Documents."

DOE - See authorities.

NASA - See Handbook NHB 2200.2.

NTIS - Leave blank.

Block 12b. Distribution Code.

DOD - Leave blank.

DOE - Enter DOE distribution categories from the Standard Distribution for Unclassified Scientific and Technical Reports.

NASA - Leave blank.

NTIS - Leave blank.

Block 13. Abstract. Include a brief (*Maximum 200 words*) factual summary of the most significant information contained in the report.

Block 14. Subject Terms. Keywords or phrases identifying major subjects in the report.

Block 15. Number of Pages. Enter the total number of pages.

Block 16. Price Code. Enter appropriate price code (*NTIS only*).

Blocks 17. - 19. Security Classifications. Self-explanatory. Enter U.S. Security Classification in accordance with U.S. Security Regulations (i.e., UNCLASSIFIED). If form contains classified information, stamp classification on the top and bottom of the page.

Block 20. Limitation of Abstract. This block must be completed to assign a limitation to the abstract. Enter either UL (unlimited) or SAR (same as report). An entry in this block is necessary if the abstract is to be limited. If blank, the abstract is assumed to be unlimited.

FOREWORD

Opinions, interpretations, conclusions and recommendations are those of the author and are not necessarily endorsed by the US Army.

Where copyrighted material is quoted, permission has been obtained to use such material.

Where material from documents designated for limited distribution is quoted, permission has been obtained to use the material.

Citations of commercial organizations and trade names in this report do not constitute an official Department of Army endorsement or approval of the products or services of these organizations.

In conducting research using animals, the investigator(s) adhered to the "Guide for the Care and Use of Laboratory Animals," prepared by the Committee on Care and Use of Laboratory Animals of the Institute of Laboratory Resources, National Research Council (NIH Publication No. 86-23, Revised 1985).

For the protection of human subjects, the investigator(s) adhered to policies of applicable Federal Law 45 CFR 46.

In conducting research utilizing recombinant DNA technology, the investigator(s) adhered to current guidelines promulgated by the National Institutes of Health.

In the conduct of research utilizing recombinant DNA, the investigator(s) adhered to the NIH Guidelines for Research Involving Recombinant DNA Molecules.

In the conduct of research involving hazardous organisms, the investigator(s) adhered to the CDC-NIH Guide for Biosafety in Microbiological and Biomedical Laboratories.

Bonnie C. Harkness 24 Oct 1995
PI - Signature Date

Table of Contents

Front Cover	page 1
SF 298 Report Documentation page	2
Foreword	3
Table of Contents	4
Progress Report	
Introduction	5
Work in Progress	6

INTRODUCTION

The main objective of this infrastructure project was to expand a population-based mammography registry to include every mammogram performed in practices in a 24 county area of North Carolina, which has a large rural, and black rural population. The goal is to link pathology data, mammography diagnostic data, outcome data and Quality data to study the patterns or use of mammography, and the patterns of practice of mammography in this distinct geographic region.

Previous to this application, a mammographic data retrieval system was developed by the investigators, and feasibility work performed to get it into practices outside of the academic medical center. The project was proposed for an area that was already organized for pathology retrieval for the Breast Cancer SPORE. Having the infrastructure in place would allow research on mammography outcomes, with the ability to compare women served by the CDC BCCCP program and to study differences between rural and urban, and black and white women.

WORK IN PROGRESS

In the first year we have accomplished much according to our statement of work in the application.

Task 1: Organizational Development (0-6 months.)

- a. Create oversight committee: to set policy, definitions and time tables, and promotional guidance for registry.*
- b. Create executive committee for practice recruitment: to design outreach program, and publicity for recruitment.*
- c. Create executive committee for pathologist recruitment: to establish approach for pathologist recruitment.*

We have created an advisory committee, which has met as a group one time, and been called for advice on individual basis. We have work groups that have guided us in our recruitment of practices and pathologists. We are presently working with the NCCCR and the NC Association of Tumor Registrars to create a mechanism for receiving all benign pathology data in addition to the cancer pathology data.

Task 2: Customize and install computer network and programs (0-12 months).

- a. Design and install computer interface and linking programs to enable linkage to Lineberger CCC and NCCCR.*
- b. Establish confidentiality and quality control protocols*

Much has been accomplished in improving the applications software that is used in the practices for collection and tracking of mammography data.

The following tasks have been accomplished with the **Carolina Mammography DataSystem Software** since January 1, 1995:

- Original software code has been documented with directional, technical, and expletive statements for ease in maintenance and development tasks
- The primary mammogram database has been redesigned and divided into linked subsidiary databases to accommodate a growing variable data set recorded by the software
- Minor software enhancements have been made to the streamlined version of the software per the request of the pilot site
- Major software enhancements have been made to the general version to reflect data decisions rendered by the National Breast Cancer Surveillance Consortium. Additionally, screen designs have been altered to expedite data entry and promote site usability.
- New installation features have been added to the general distributed version that allows each site to customize the software to record relevant personnel and satellite location center information for reporting purposes
- The pathology user interface has been revamped and the ensuing changes made to the pathology database. An accompanying report feature has also been implemented to organize and display pathology data entered by the site in hardcopy format.
- A reporting module has been designed and instituted that helps facilities meet Federal Drug Administration/ Mammography Quality Standards Act. This module produces a monthly mammogram report outlining patients with positive mammograms, mammogram interpretation codes, and recommended follow-up procedures. It also generates a monthly summary report by individual radiologist which summarizes screening and diagnostic mammograms conducted on a monthly basis with summary data of the interpretation codes by the number of recommended follow-up tests ordered. Lastly, a referring physicians report can be generated for patients with positive mammogram results.
- A query system has been designed and coded that will track mammogram patients who have not returned for a recommended follow-up visit. This system provides the site with needed flexibility to categorize patients by type of recommended follow-up exam over any given time period within the database along with the display mode (i.e. Printed Report, Screen Display, or Text File saved to disk).

Over the past 12 months we have done extensive work to create, document, test and now are using a quality control system. All data received is run against the QC programs which check for inconsistent and missing data, and print reports which we send back to the practices for correction or clarification. The practices correct on the reports, and we edit the data at the research site. All data has identifying information stripped and unique ID's assigned. We are working on a plan to do spot double entry of data to test for error rates of data entry.

We have strict rules for guaranteeing confidentiality to the best of our ability. No reports sent to practices are kept on file in our research site, the only copy goes to the practice. We do not have any analysis files that are linked to pathology, or have identifying information. The original disks that are sent to us with downloaded data are kept in a locked cabinet.

We have been assured by the NC counsel for the public health department that a new state law that went into effect on 1 October 1995 protects the data from being accessed under the public freedom of information law. We lock our computers when not in use. In addition we are working within the National Breast Cancer Surveillance Consortium to apply for a US Public Health service certificate of confidentiality. We are pursuing every avenue open to us to guarantee confidentiality and protection of data, to the best of our ability.

Task 3: Enroll Mammography practices and pathologists into registry (0-24 months)

- a. Contact every mammography practice in 24 counties to enroll in registry
- b. Demonstrate and install mammography database in interested practices
- c. Arrange for data transfer in practices already using a data system
- d. Arrange for paper data collection and transfer in practices choosing this option.e.

Establish process with each pathology site for acquisition of all breast pathology data: and expand process with those already cooperating with NCCCR, to acquire benign breast pathology

We have been very successful in recruitment so far. We have enrolled 29 practice in 15 counties as of 10/25/95. All facilities in the 24 counties have been contacted. We will continue to bring the remaining practices into the registry steadily. The practices actively participating at the present time are listed below by county, and practice type.

Practice Type		City	County
radiology unless otherwise specified			
1)	Hospital	Burlington	Alamance
2)	Private	Washington	Beaufort
3)	Hospital	Pungo	Beaufort
4)	Hospital	Windsor	Bertie
5)	Hospital	Siler City	Chatham
6)	Private	Durham	Durham
7)	Ob/Gyn Practice	Durham	Durham
8)	Medical Center	Durham	Durham
9)	Hospital	Smithfield	Johnston
10)	Private	Smithfield	Johnston
11)	Hospital	Williamston	Martin
12)	Hospital	Pinehurst	Moore
13)	Radiology	Pinehurst	Moore
14)	Hospital	Rocky Mount	Nash
15)	Hospital	Rocky Mount	Nash

16)	Family Practice	Hillsborough	Orange
17)	Private	Chapel Hill	Orange
18)	Ob/Gyn Practice	Chapel Hill	Orange
19)	Academic Hospital	Chapel Hill	Orange
20)	Ob Gyn practice	Greenville	Pitt
21)	Medical Practice	Greenville	Pitt
22)	Hospital	Plymouth	Washington
23)	AFB Hospital	Goldsboro	Wayne
24)	Family Medicine	Raleigh	Wake
25)	Family Practice	Raleigh	Wake
26)	Private	Raleigh	Wake
27)	Hospital	Cary	Wake
28)	Private	Raleigh	Wake
29)	Hospital	Wilson	Wilson

In addition we have linked up with the North Carolina Breast Cancer Study (PI, Beth Newman, funding agency, NCI under the Breast Cancer SPORE), and the North Carolina Central Cancer Tumor Registry (NCCCR), and get weekly delivery of all fast reported breast cancers in the 24 counties.

The following materials have been developed in support of the data system being used by our participating practices.

- Data Management Guide
- Data collection manual--describes how to collect data on paper, definitions of interpretation codes, follow-up recommendations, etc.
- CMDS (Data system) User's guide
- Data Dictionary
- Documentation describing the QC reports for mammo facilities

Task 4: Operate and Maintain Registry (0-36 months)

- a. On-going data cleaning and entry*
- b. On-going quality control*
- c. Linkage to NC-CCR and Lineberger CCC*
- d. Respond to requests for shared use of registry data (beginning at 36 months)*

We are 'in business', actively bringing on new sites, running our QC reports, editing data, and feeding data back to the practices. We have pathology data arriving through the Lineberger Breast Cancer SPORE and the NCCCR, and are building a pathology database. We are optimistic that by this time next year, we will have data to report, as many practices will have been sending data for a year.

In addition to all this activity, the creation of this infrastructure enabled us to successfully compete to be funded by the National Cancer Institute to become part of the National Breast Cancer Consortium. This moves the project from being important to NC, and to the nation as a whole. The National Consortium is creating a core dataset that will allow pooling of data from 9 projects similar to CMR to be able to study screening mammography on a national scale, with the ability to compare different racial/ethnic groups, different locales and different urban/rural settings. It is a very exciting project, and we are thrilled to be a part of it. We have been very careful to avoid overlap of funding. The NCI monies allow us to begin research projects off this data, and guarantee the continuation of the registry beyond the 3 years of support under this DOD funded project. It is what one would hope for when building an infrastructure. We have plans to study the biology of screen-detected vs interval cancers in the diverse population we are studying, and have support to study follow-up of women with positive mammograms to treatment.